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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,683	08/25/2003	Pamela Reed		2901
7590	11/16/2004		EXAMINER	
Pamela Reed P.O. Box 2309 Knoxville, TN 37901			PAK, JOHN D	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/647,683	REED ET AL.
	Examiner	Art Unit
	JOHN PAK	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>8/25/03</u> .	6) <input type="checkbox"/> Other: _____.

Claims 1-6 are pending in this application.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barton et al. (WO 98/10744) in view of Block, Chemical Abstracts 96:447 and 130:235102.

Barton et al. disclose a formulation that contains, *inter alia*, hydrogen peroxide, nonoxynol-9 and excipients, for topical delivery (see pages 4-5, "Manufacturing Formula"; and the rest of page 5). Hydrogen peroxide is listed as a sterilizing agent (page 4, last line). The formulation is disclosed to be effective against viral and bacterial sexually transmitted diseases, including such diseases from the human papilloma virus (page 2, lines 4-6). The liquid vehicle "comprises a viscous, slightly sticky material, having a viscosity and physical properties very similar to that of natural saliva" (page 3, lines 1-3). Such bases or vehicles include cellulose derivatives, e.g. carboxymethyl cellulose (page 3, lines 8-9). Capsules, tablets, and other "alternative delivery/packaging systems" in cases of genital/genital contact are suggested (page 4, lines 3 and 12).

Block establishes the well known fact that hydrogen peroxide is a broad-spectrum microbicide, with activity against a wide range of organisms: bacteria, yeasts, fungi, viruses and spores (pages 168-171, in particular, page 169, left column, first paragraph under "Antimicrobial Activity of Hydrogen Peroxide"; see also Table 9-1 on pages 169-170). Activity against the Hepatitis B virus is also known (pages 460-461, in particular, page 461, right column, first two full paragraphs).

Chemical Abstracts 96:447 discloses the antitumor activity of hydrogen peroxide.

Chemical Abstracts 130:235102 discloses the mechanism by which hydrogen peroxide provides antiviral activity. Infected cell and its neighbors are eliminated.

While the cited references do not expressly disclose treatment of HPV-induced "tumors" such as verrucae, plantar, flat or genital warts with hydrogen peroxide (in gel form or otherwise), the references nonetheless combine to fairly suggest the claimed invention. Barton et al. clearly teach the use of hydrogen peroxide-containing formulations to treat viral STDs from the human papillomavirus and provide prophylaxis of the same. Even though nonoxynol-9 is used by Barton et al., applicant should note that applicant's claims have no requirement to exclude such additional active ingredient. Therefore, use of nonoxynol-9 does not detract from the fact that Barton's formulation still explicitly disclose the use of hydrogen peroxide for treatment and prophylaxis of STDs from human papillomavirus. Given the well documented broad-spectrum

microbicidal activity of hydrogen peroxide against many different viruses, taken with the teaching that hydrogen peroxide has antitumor activity, the ordinary skilled artisan in this field would have expected the hydrogen peroxide-containing formulation by Barton et al. to possess treatment efficacy for HPV-induced tumors, such as genital warts and other types of warts. As for applying in the form of a gel, it is noted that Barton et al. disclose viscous vehicles such as carboxymethyl cellulose and other alternative delivery systems. It is the Examiner's position that applicant's "gel" language is fairly met by Barton's disclosure. Additionally, one having ordinary skill in the art would have been motivated to apply Barton's formulation in the form of a gel with the expectation that the gel would not run off as quickly as a less viscous formulation, particularly in genital/genital contact (Barton et al., page 4, line 11).

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

For these reasons, all claims must be refused at this time.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.



JOHN PAK  
PRIMARY EXAMINER  
(703) 272-1600